K120993

PREMARKET NOTIFICATION

JUL 26 2012

510(k) Summary

GammaMedplus™ iX and GammaMedplus™ 3/24 iX

As required by 21 CFR 807.92

Submitter's Name:	Varian Medical Systems 3100 Hansen Way, m/s E110 Palo Alto CA94304
	Contact Name: Ms Vy Tran, Vice President, Regulatory Affairs and Quality Systems Phone: 650/424.5731 Fax: 650/842.5040 vy.tran@varian.com Date: 23rd March 2012
Proprietry Name:	GammaMedplus™ iX and GammaMedplus™ 3/24 iX
Classification Name:	Remote controlled radionuclide applicator system 21CFR892.5700 Class II
Common/Usual Name:	GammaMedplus™ iX afterloader, GammaMedplus™ iX, GammaMedplus™ iX series GammaMedplus™ iX series afterloader systems, GammaMedplus™ iX series afterloaders
Predicate Devices:	GammaMedplus iX Series HDR Afterloaders (K071381) and Nucletron MicroSelectron V3 (K061354).
Device Description:	The GammaMedplus iX Series afterloader systems are computer controlled remote electro/mechanical systems used for medical purposes, for placing a cable incorporating an irradiated iridium seed internally or close by a malignant tumor or tumor bed in a practice known as brachytherapy.
Indications for Use:	The GammaMedplus iX™ Series is indicated for use in the treatment of both benign and malignant disease, for both curative and palliative intent, in the delivery of High Dose Rate (HDR) and Pulsed Dose Rate (PDR) remote-controlled brachytherapy.

Technological Characteristics:

	Nucletron MicroSelectron V3	*GammaMedplus™ iX, (with Console Software version 1.1)*	*GammaMedplus™ iX, (with Console Software version 1.2)*
Predicate Device Clearance Number:	K061354	K071381	N/A
Indications for Use	The MicroSelectron V3 is intended to enable an operator to apply, by remote control, a radionuclide source into the body (including Interstitial, Intracavitary, Intraluminal, Bronchial, Endovascular, and Intra-operative) or to the surface of the body for radiation therapy.	Both the GammaMedplus iX and GammaMedplus 3/24 iX are indicated, in the treatment of both benign and malignant disease, for both curative and palliative intent, in the delivery of remote controlled high dose rate brachytherapy for conditions anywhere in the body when brachytherapy treatment is indicated.	The GammaMedplus™ iX Series is indicated for use in the treatment of both benign and malignant disease, for both curative and palliative intent, in the delivery of remote-controlled High Dose Rate (HDR) and Pulsed Dose Rate (PDR) brachytherapy.
Intended use	The MicroSelectron V3 is intended to enable an operator to apply, by remote control, a radionuclide source into the body (including Interstitial, Intracavitary, Intraluminal, Bronchial, Endovascular, and Intra-operative) or to the surface of the body for radiation. therapy.	The GammaMedplus iX Series is computer controlled remote HDR Afterloader used to place a high activity radioactive source within a needle(s) or applicator(s) which have previously been placed for a specified clinical purpose in a patient. The radioactive source (enclosed within the wire/cable) is driven via coupling catheters (Transfer Guide Tubes) from the Afterloader into needles or applicators within or on the patient. The length of time and position that the High Dose Rate source spends within the needle or applicator is controlled in accordance with an Irradiation Treatment Prescription.	The GammaMedplus iX™ Series is intended for use in the treatment of both benign and malignant disease, for both curative and palliative intent, in the delivery of remote-controlled High Dose Rate (HDR) and Pulsed Dose Rate (PDR) brachytherapy.
Base Area	80 cm x 46 cm	57,5 cm x 51 cm	57,5 cm x 51 cm
Height	98 cm – 138 cm	105 cm-145 cm	105 cm-145 cm

	Nucletron MicroSelectron V3	*GammaMedplus™ iX, (with Console Software version 1.1)*	*GammaMedplus™ iX, (with Console Software version 1.2)*
Adjustable height position measured in the center of the indexer	90.8cm- 138.0cm	90 cm-130 cm	90 cm-130 cm
Weight	120 kg	130 kg	130 kg
Transportable (USDOT-7A; Type A)	Yes	Yes	Yes
Power Supply	90-130V; 60 Hz, or 190-250V; 50 Hz	230/115/100V 50-60 Hz	230/115/100V 50-60 Hz
Mobile	Yes	Yes	Yes
HDR	Yes	Yes	Yes
PDR	Yes	No	Yes for GammaMedplus iX No for GammaMedplus 3/24 iX
Number of Channels	6, 18, 30	24 for GammaMedplus iX 5 for GammaMedplus 3/24 iX	24 for GammaMedplus iX 5 for GammaMedplus 3/24 iX
Shielding	Tungsten.	Tungsten	Tungsten
Maximum shielding activity	518 GBq / 14 Ci	555 GBq / 15 Ci	555 GBq / 15 Ci
Maximum treatment activity	518 GBq / 14 Ci	555 GBq / 15 Ci	555 GBq / 15 Ci
Max. exposure rate at 1m distance containing the maximum activity	<0.15 μSv/hr, when containing a 10 Ci source	0.3 mrem/hr (3 μSv/hr)	0.3 mrem/hr (3 μSv/hr)
Dwell positions per each channel	48	60	60
Area radiation monitor (integrated GM counter)	Yes	Yes	Yes
Maintained treatment data during power failure (battery powered RAM)	Yes	Yes	Yes
Simulator source	Yes	Yes	Yes
Verification of channel length	No	Yes	Yes

	Nucletron MicroSelectron V3	*GammaMedplus™ iX, (with Console Software version 1.1)*	*GammaMedplus™ iX, (with Console Software version 1.2)*
Verification of applicator connection	No	Yes*	Yes
Source positioning	Proximal to distal	Distal to proximal	Distal to proximal
Max. source position error over treatment length	+/- 1mm per position	0.35 % referring to 600 mm	0.35 % referring to 600 mm
Emergency container for the source	Yes	Yes	Yes
Response to emergency signal	Automatic source retraction	Automatic source retraction	Automatic source retraction
Emergency manual retraction	Yes	Yes	Yes
Isotope	Ir-192	Ir-192	Ir-192
Source			
Maximum activity	518 GBq / 14 Ci	555 GBq / 15 Ci	555 GBq / 15 Ci
Maximum treatment activity	518 GBq / 14 Ci	555 GBq / 15 Ci	555 GBq / 15 Ci
Capsule dimensions (length x ∅)	4,50 x 0.9 mm	4,52 x 0.9 mm	4,52 x 0.9 mm
Active dimensions (length x ∅)	3,5 x 0.6 mm	3,5 x 0.6 mm	3,5 x 0.6 mm
Source extension length	1500 mm	1300 mm	1300 mm
Operator console			
Operating console with Personal Computer and Printer	Yes	Yes	Yes
Keyswitch control	Yes	Yes	Yes
Operating voltage	90-130 V, or 190-250 V	24 V from GammaMedplus iX	24 V from GammaMedplus iX

	Nucletron MicroSelectron V3	*GammaMedplus™ iX, (with Console Software version 1.1)*	*GammaMedplus™ iX, (with Console Software version 1.2)*
Control Software	**microSelectron™ Treatment Control Software**	**iX Console Software Version 1.1**	**iX Console Software Version 1.2**
Plan Import	Ability to import data from Nucletron brachytherapy treatment planning systems.	Ability to accept treatment plans from any planning system that produces plans complying with the defined format.	Ability to automatically record some treatment status/history with Aria patient management system (Console software version 1.1) Ability to export treatment delivery data via a DICOM treatment delivery record. (Console software version 1.2)
Plan Creation	Available	Available	Available
Source Decay Calculation	Once daily	Once daily	Once daily
Error Reporting	Error code or status messages displayed in text, accompanied by an indication of the action required.	Error code or status messages displayed in text, accompanied by an indication of the action required.	Error code or status messages displayed in text, accompanied by an indication of the action required.
Report Generation	Treatment report includes an overview of all treatment-related information.	Treatment report includes an overview of all treatment-related information.	Treatment report includes an overview of all treatment-related information.
Plan Editing	Dwell positions may be programmed manually.	Dwell positions may be programmed manually	Dwell positions may be programmed manually
Full-Screen Operation	No full screen	Disallows access to windows operating system.	Disallows access to windows operating system
Workflows	Workflow-based treatment delivery	Workflow-based treatment delivery.	Workflow-based treatment delivery
Security	Key and password protected	Password-based user access.	Password-based user access.
Physics Test Plans	Support for physics test plans	Support for physics test plans	Support for physics test plans
Startup Checks	Automatic self-test when Treatment Control System is switched on.	Startup checks	Startup checks

	Nucletron MicroSelectron V3	*GammaMedplus™ iX, (with Console Software version 1.1)*	*GammaMedplus™ iX, (with Console Software version 1.2)*
Service Access	Service-only access mode, with features for adjusting certain parameters on the afterloader directly from the console.	Service-only access mode, with features for adjusting certain parameters on the afterloader directly from the console.	Service-only access mode, with features for adjusting certain parameters on the afterloader directly from the console..
User Access Rights	System access can be customized for specific authorization.	Privilege-based user access rights, for multiple users.	Privilege-based user access rights, for multiple users
Patient Privacy	Has several features for protecting patient privacy, including encryption of patient identification information and data disclosure reporting.	Has several features for protecting patient privacy, including encryption of patient identification information and data disclosure reporting.	Has several features for protecting patient privacy, including encryption of patient identification information and data disclosure reporting
System Data Display	Continuous display of critical system data, including pending errors, remaining wire cycles, days since last source exchange, and most-recently calculated source strength.	Continuous display of critical system data, including pending errors, remaining wire cycles, days since last source exchange, and most-recently calculated source strength.	Continuous display of critical system data, including pending errors, remaining wire cycles, days since last source exchange, and most-recently calculated source strength.
Error / Event Logging	System logbook can be displayed by date, code, and type.	Log of all recent system errors and events.	Log of all recent system errors and events.
Partial Treatment Options	Partial treatment options	Partial treatment options	Removed "redistribute undelivered portion" partial treatment option.
Error Message Annotation	Each system message can be customized to user's requirements.	Error message annotation, for site-specific error recovery actions.	Error message annotation, for site-specific error recovery actions.
Fraction Editing	Support for fraction adding and modification	Support for fraction adding and modification	Disallowed if the fraction contains dose information.
Standard Plans	Support for standard plans	Support for standard plans	Support for standard plans
Console Data Backup	Database backup and retrieval	Manual and automatic console data backup options.	Manual and automatic console data backup options.
Applicator Definition	Basic applicator definition, including number of channels, channel names, and channel lengths.	Basic applicator definition, including number of channels, channel names, and channel lengths.	Basic applicator definition, including number of channels, channel names, and channel lengths.

	Nucletron MicroSelectron V3	*GammaMedplus™ iX, (with Console Software version 1.1)*	*GammaMedplus™ iX, (with Console Software version 1.2)*
Source Exchange Record	Source information recorded, including date of last exchange, and number of source transfers.	On-going record of all source exchanges, including date, strength, and number of cycles.	On-going record of all source exchanges, including date, strength, and number of cycles.
Remote service access	Not available	Not available	Allows Varian service engineers to log into the console remotely.

* Channels 20 to 24 of the GammaMedplus iX and channels 23 and 24 of the GammaMedplus 3/24 iX do not verify the applicator connection. These channels support use of the GammaMedplus 3/24 with applicators that may not withstand the force of the push test.

Non Clinical Tests For each device, in every mode of use, a full set of verification and validation tests were performed on every pertinent aspect of the software and hardware to determine the safe functioning of the device.

Clinical Tests No Clinical tests have been included in this pre-market submission.

Conclusions All the tests that were performed met the applied pass criteria. Varian considers the device to be safe and effective and to perform as well or better than the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

JUL 26 2012

Ms. Vy Tran
Vice President, Regulatory Affairs and Quality Systems
Varian Medical Systems, Inc
3100 Hansen Way
PALO ALTO CA 94304

Re: K120993
Trade/Device Name: GammaMedplus iX and GammaMedplus 3/24 iX afterloaders
(GammaMedplus iX™ Series Brachytherapy Afterloaders).
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: June 18, 2012
Received: June 20, 2012

Dear Ms. Tran:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): _____

Device Name: GammaMedplus iX and GammaMedplus 3/24 iX afterloaders
(GammaMedplus iX™ Series Brachytherapy Afterloaders).

Indications for Use:

The GammaMedplus iX™ Series is indicated for use in the treatment of both benign and malignant disease, for both curative and palliative intent, in the delivery of High Dose Rate (HDR) and Pulsed Dose Rate (PDR)remote-controlled brachytherapy.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K120493